

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

WE THE PATRIOTS USA, INC.,
DIANE BONO,
MICHELLE MELENDEZ,
MICHELLE SYNAKOWSKI,
Plaintiffs,
v.

No. 1:21-cv-4954 (WFK) (RER)

KATHLEEN HOCHUL – GOVERNOR
OF NEW YORK; HOWARD
ZUCKER, M.D. - COMMISSIONER,
NEW YORK STATE DEPARTMENT
OF HEALTH
Defendants.

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS PLAINTIFFS' COMPLAINT**

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Defendants, Governor Kathy Hochul and Acting Commissioner of the New York State Department of Health Mary T. Bassett, M.D., M.P.H.,¹ sued in their official capacities, respectfully submit this memorandum of law, together with the accompanying Declaration of Todd A. Spiegelman, dated January 26, 2022 (“Spiegelman Decl.”), and the exhibits annexed thereto, in support of Defendants’ motion to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) in its entirety and with prejudice.

Preliminary Statement

The State of New York, along with the rest of the world, continues to confront the greatest public health crisis in living memory. As reported by the CDC, the COVID-19 pandemic has caused over 62,000 deaths in New York alone. The impact of the disease has been particularly devastating in the healthcare sector, where already-vulnerable patients and residents are at greater risk of severe harm from any infection, and where the spread of the virus among healthcare workers can lead to a vicious cycle of staff shortages and deterioration of patient care.

In light of the distinct concerns raised by the spread of COVID-19 in the healthcare sector, the New York State Department of Health (“DOH”) promulgated an emergency rule requiring COVID-19 vaccinations for certain healthcare workers, 10 N.Y.C.R.R. § 2.61 (the “Emergency Rule” or “Rule”): namely, any worker whose activities could potentially expose other personnel or patients to COVID-19 if he or she were infected. Like preexisting vaccination requirements for measles and rubella that have long applied to healthcare workers, DOH’s Emergency Rule contains only a narrow medical exemption to protect employee health, and does not provide for any other exemption—including a religious exemption.

¹ Dr. Bassett was appointed Acting DOH Commissioner on December 1, 2021 and is automatically substituted as a defendant for former DOH Commissioner Zucker pursuant to Federal Rule of Civil Procedure 25(d).

Plaintiffs are three individual healthcare workers and a membership organization who claim that the Emergency Rule (1) violates their right to freely exercise religion under the First Amendment to the United States Constitution because the rule lacks a religious exemption; and (2) violates their Fourteenth Amendment due process rights to privacy and medical freedom.

This Court previously denied Plaintiffs' motion for a temporary restraining order and preliminary injunction against enforcement of the Rule. The Second Circuit affirmed this Court's decision and the Supreme Court denied Plaintiffs' motion for an emergency stay of the Rule.

In its detailed, 46-page opinion, the Second Circuit held that Plaintiffs were unlikely to succeed on the merits of any of their claims. *We The Patriots v. Hochul*, 17 F.4th 266, 273 (2d Cir.), *opinion clarified*, 17 F.4th 368 (2d Cir. 2021). Indeed, as shown herein the Complaint does not state any cognizable claims against Defendants.

First, courts have repeatedly upheld vaccination requirements against various constitutional challenges—including claims under the Free Exercise Clause—for well over a century. Both this Court and the Second Circuit have squarely recognized that religious exemptions from mandatory vaccination laws are not required by the First Amendment. *Phillips v. City of New York*, 27 F. Supp. 3d 310, 312-13 (E.D.N.Y. 2014) (Kuntz, J.), *aff'd*, 775 F.3d 538, 543 (2d Cir. 2015). And both this Court and the Second Circuit have rejected substantive due process claims challenging vaccination mandates. *Id.*

Second, DOH's vaccination requirement is neutral and generally applicable. Thus, it is subject only to rational basis review which it "easily meets." *Patriots*, 17 F.4th at 290. The Emergency Rule is neutral because it does not expressly target religious activity and was not promulgated due to religious hostility. The public record demonstrates that DOH simply followed long-standing practice in not including a religious exemption to the Rule, and

Plaintiffs' claims of an ulterior motive are implausible. The Emergency Rule is generally applicable because it extends to all covered personnel at healthcare facilities who can safely receive a vaccination regardless of any philosophical, personal, or religious objections they may have. And the Rule plainly satisfies rational basis review inasmuch as it serves a legitimate interest in stemming the spread of COVID-19 among healthcare workers and their vulnerable patients, and it is reasonably related to that interest. Vaccinations are among the most effective ways to prevent serious illness from COVID-19 and to limit transmissibility to others.

Lastly, Plaintiffs' claim that the Emergency Rule violates their fundamental rights is unavailing. The Second Circuit held in this case that the Constitution does not contain a fundamental right that would invalidate vaccine requirements that are taken in response to a public health crisis. *Id.* at 293.

Accordingly, DOH's motion to dismiss should be granted in its entirety and the Complaint should be dismissed.

Statement of Facts

A. New York's History of Vaccination Requirements

New York has long been a national leader in mandating vaccinations to protect against the spread of communicable disease. New York began requiring school-age children to be vaccinated against smallpox in the 1860s. *See* James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, 851 (2002). The Legislature regularly updates compulsory school vaccination laws when new vaccines become available, and in 2019 it eliminated any religious exemption from these requirements. *See* Public Health Law ("PHL") § 2164, *as amended by* L. 2019, ch. 35, §§ 1, 2.

New York has also regularly imposed vaccination requirements on healthcare workers.

For example, hospital employees who pose a risk of transmission to patients must be immunized against measles and rubella, and religious exemptions are not permitted. *See* 10 N.Y.C.R.R. § 405.3(b)(10)(i)-(ii). Similar rules apply to healthcare workers in long-term care facilities and other institutions.² These regulations have been in place in similar form since at least 1993. *See* Health and Immunization of Employees of Medical Facilities and Certified Home Health Agencies, 15 N.Y. Reg. 15, 20 (Mar. 24, 1993) (proposed regulation for rubella and measles vaccinations), Spiegelman Decl., **Exhibit A**; Immunization of Health Care Workers, 15 N.Y. Reg. 9, 10 (Sep. 8, 1993) (notice of adoption), Spiegelman Decl., **Exhibit B**.

New York’s mandatory vaccination programs reflect the consensus view that “immunizations are among the most effective preventative measures to preserve and protect the public health” and that compliance with the “childhood and adult vaccination schedules” promulgated by public health authorities is essential to preventing the spread of communicable diseases. Ch. 603, § 1, 2005 N.Y. Laws 3379, 3379. According to the federal Centers for Disease Control and Prevention (“CDC”), the development and availability of vaccinations has been one of the most important public health advances in history.³ Polio and smallpox, previously devastating diseases, have been essentially eliminated in the United States due to vaccinations,⁴

² *See* 10 N.Y.C.R.R. §§ 415.26 (nursing home personnel), 751.6 (employees of diagnostic and treatment centers), 763.13 (personnel of home health agencies, long term home health care programs, and AIDS home care programs), 766.11 (personnel of licensed home care services agencies), 794.3 (hospice personnel), 1001.11 (assisted living residences personnel).

³ CDC, *Achievements in Public Health, 1900-1999: Impact of Vaccines Universally Recommended for Children—United States, 1990-1998*, 48 Morbidity & Mortality Wkly. Rep. 243, 243-48 (1999) (“CDC Achievements”), available at <https://www.cdc.gov/mmwr/preview/mmwrhtml/00056803.htm> (last visited January 26, 2022). On a motion to dismiss, the court may take judicial notice of “relevant matters of public record,” *Giraldo v. Kessler*, 694 F.3d 161, 164 (2d Cir. 2012), such as public health statistics reported by governmental agencies and guidance and advisories from public health organizations. *See Geller v. De Blasio*, No. 20-cv-3566, 2020 WL 2520711, at *2 n.1 (S.D.N.Y. May 18, 2020) (taking judicial notice of public health statistics reported by New York City); *Geller v. Cuomo*, No. 20-cv-4653, 2020 WL 4463207, at *1 n.1, n.2 (S.D.N.Y. Aug. 3, 2020) (taking judicial notice of guidance from the CDC, data from John Hopkins University regarding COVID-19, and guidance from the World Health Organization (“WHO”); *see also* Fed. R. Evid. 201(b) (courts may take judicial notice of facts “not subject to reasonable dispute.”).

⁴ CDC *Achievements*, *supra*.

and the incidence of seven other serious diseases has similarly been reduced in the United States by nearly one hundred percent through compulsory vaccination.⁵

Where vaccination is not so widespread, vaccine-preventable diseases continue to cause death on a very large scale. For example, approximately one million people outside the United States die every year from measles.⁶ Even in the United States, the incidence of various communicable diseases has grown due to a recent increase in the number of parents refusing to vaccinate their children. As a result, diseases such as measles have reappeared throughout the country, although they were once thought to be nearly eradicated here.⁷

B. The COVID-19 Pandemic

As the Court is aware, COVID-19 is a highly infectious and potentially deadly respiratory illness that spreads easily from person to person. It was first detected by the WHO in December 2019.⁸ On March 11, 2020, the WHO declared COVID-19 a pandemic,⁹ and two days later, President Trump declared a national emergency.¹⁰ In early January of this year, the global death toll passed 5.5 million people.¹¹ And in the United States alone, COVID-19 has infected more than 71 million people and claimed over 860,000 lives,¹² including at least 888,000 infections and 3,400 deaths among healthcare workers.¹³

⁵ *Id.*

⁶ *Id.*

⁷ CDC, Vaccines for Your Children, available at *Parent's Guide to Childhood Immunizations* (2014), available at <https://www.cdc.gov/vaccines/parents/why-vaccinate/vaccine-decision.html> (last visited Jan. 26, 2022).

⁸ WHO, *Listings of WHO's Response to COVID-19* (last updated Jan. 29, 2021), available at <https://www.who.int/news/item/29-06-2020-covidtimeline> (last visited Jan. 26, 2022).

⁹ *Id.*

¹⁰ Press Release, Federal Emergency Mgmt. Agency, *COVID-19 Emergency Declaration*, available at <https://www.fema.gov/press-release/20210318/covid-19-emergency-declaration> (last visited Jan. 22, 2022).

¹¹ WHO, WHO Coronavirus (COVID-19) Dashboard, available at <https://covid19.who.int/> (last visited January 26, 2022).

¹² CDC, *COVID Data Tracker*, available at https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days (last visited January 26, 2022).

¹³ See CDC, *COVID Data Tracker: Cases & Deaths Among Healthcare Personnel*, available at <https://covid.cdc.gov/covid-data-tracker/#health-care-personnel> (last visited Jan. 22, 2022).

During the summer of 2021, the United States experienced a third wave of COVID-19 due to the spread of the Delta variant of the virus, which is more than twice as contagious as earlier variants and quickly became the predominant variant in the United States.¹⁴ The increased circulation of the Delta variant coincided with a marked increase in hospitalizations.¹⁵

On December 1, 2021, the first case of the Omicron variant was confirmed in the United States.¹⁶ The CDC identified the potential for a rapid increase in infections from this highly contagious variant,¹⁷ and the emergence of Omicron has coincided with a record number of infections in the United States—New York in particular—in December 2021 and January 2022.¹⁸

In light of the emergency caused by the COVID-19 pandemic, the U.S. Food and Drug Administration (“FDA”) issued emergency use authorizations for the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines in December 2020 and February 2021 for certain age groups.¹⁹ On August 23, 2021, the FDA granted full regulatory approval for the Pfizer vaccine for those 16 and older.²⁰

¹⁴ CDC, Delta Variant: What We Know About the Science (Updated Aug. 26, 2021), available at <https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html> (last visited Jan. 26, 2022).

¹⁵ CDC, Covid Data Tracker, available at <https://covid.cdc.gov/covid-data-tracker/#hospitalizations-severity> (last visited Jan. 26, 2022).

¹⁶ CDC, Omicron Variant: What You Need to Know (Updated Dec. 20, 2021), available at <https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html> (last visited Jan. 26, 2022).

¹⁷ CDC, Potential Rapid Increase of Omicron Variant Infections in the United States (Updated Dec. 20, 2021), available at <https://www.cdc.gov/coronavirus/2019-ncov/science/forecasting/mathematical-modeling-outbreak.html> (last visited Jan. 26, 2022).

¹⁸ CDC, Covid Data Tracker, available at https://covid.cdc.gov/covid-data-tracker/#trends_dailycases (last visited Jan. 26, 2022).

¹⁹ Press Release, FDA, *FDA Takes Key Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for First COVID-19 Vaccine*, available at <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19> (last visited Jan. 26, 2022); Press Release, FDA, *FDA Takes Additional Action in Fight Against COVID-19 by Issuing Emergency Use Authorization for Second COVID-19 Vaccine*, available at <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-in-fight-against-covid-19-by-issuing-emergency-use-authorization-for-second-covid-19-vaccine> (last visited Jan. 26, 2022); Press Release, FDA, *FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine*, available at <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine> (last visited Jan. 26, 2022).

²⁰ Press Release, FDA, *FDA Approves First COVID-19 Vaccine*, available at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine> (last visited Jan. 26, 2022).

Studies have shown that these vaccines are both safe and highly effective. To take just one example, a study published last fall in the New England Journal of Medicine found that the Pfizer and Moderna vaccines were “highly effective under real-world conditions in preventing symptomatic Covid-19 in health care personnel,” with an efficacy of over 88% for those personnel who were fully vaccinated.²¹

In light of the success of the COVID-19 vaccines, a broad coalition of healthcare professional organizations has called for healthcare employers to require their employees to be vaccinated, including the American Medical Association, American Nurses Association, American Academy of Pediatrics, Association of American Medical Colleges, National Association for Home Care and Hospice, American Academy of Physician Associates, American Pharmacists Association, American Public Health Association, and the Infectious Diseases Society of America.²² The Supreme Court recently observed that “healthcare workers and public health organizations overwhelmingly support” the federal government’s vaccine mandate for all healthcare facilities receiving Medicare or Medicaid funding. *Biden v. Missouri*, Nos. 21A240 & 21A241, 595 U.S. ___ (2022), 2022 WL 120950 (January 13, 2022).

C. The Emergency Rule

DOH is responsible for protecting the public health and, in particular, supervising and regulating “the sanitary aspects of . . . businesses and activities affecting public health.” PHL § 201(1)(m). Pursuant to this broad mandate, DOH acted swiftly in August 2020 to respond to the risks posed by transmission of the Delta variant in New York’s healthcare sector.

²¹ New England Journal of Medicine, *Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel*, Dec. 16, 2021, available at <https://www.nejm.org/doi/full/10.1056/NEJMoa2106599> (last visited Jan. 26, 2022).

²² Press Release, Association of American Medical Colleges, *Major Health Care Professional Organizations Call for COVID-19 Vaccine Mandates for All Health Workers*, available at <https://www.aamc.org/news-insights/press-releases/major-health-care-professional-organizations-call-covid-19-vaccine-mandates-all-health-workers> (last visited Jan. 26, 2022).

1. The DOH Commissioner’s August 18, 2021 Order for Summary Action

On August 18, 2021—prior to full FDA approval of the Pfizer vaccine—the DOH Commissioner issued an Order for Summary Action under Public Health Law § 16, which allows him to “take certain action immediately” to remedy “a condition or activity which in his opinion constitutes danger to the health of the people” for a period not to exceed fifteen days. PHL § 16; DOH, Order for Summary Action (Aug. 18, 2021), Spiegelman Decl., **Exhibit C**. The Order for Summary Action was narrow in scope, covering only hospitals and nursing homes. *See id.* at 3. It also included an exemption for individuals who “hold a genuine and sincere religious belief contrary to the practice of immunization, subject to a reasonable accommodation by the employer.” *Id.* at 5-6.

This short-term Order was superseded when, on August 26, 2021, DOH’s Public Health and Health Planning Council (the “Council”) issued the Emergency Rule at issue in this action.

2. The Council’s August 26, 2021 Emergency Rule

The Council is a 25-member advisory body to DOH made up of public health experts, physicians, academics as well as the DOH Commissioner.²³ Public Health Law § 225 confers on the Council the role of making recommendations to DOH on “any matter relating to the preservation and improvement of public health.” PHL § 225(1).

The Council adopted the Emergency Rule on August 26, 2021, three days after the FDA gave full approval to the Pfizer vaccine. Under New York law, an emergency regulation may go into effect immediately upon its filing with the New York Secretary of State and remain in effect

²³ DOH, Council Membership, *available at* https://www.health.ny.gov/facilities/public_health_and_health_planning_council/membership_list.htm (last visited Jan. 26, 2022).

for up to ninety days, at which point it must be renewed to remain in force. *See* State Administrative Procedure Act § 202(6)(b).

The Emergency Rule mandates that covered healthcare entities “continuously require” employees to be fully vaccinated against COVID-19 if they “engage in activities such that if they were infected with COVID-19, they could potentially expose other covered personnel, patients or residents to the disease.” 10 N.Y.C.R.R. § 2.61(a)(2), (c). The Emergency Rule covers a broader range of healthcare entities than had the Commissioner’s Order for Summary Action, extending to, *inter alia*, certified home health agencies, long term care service agencies, hospices and adult care facilities. *See id.* § 2.61(a)(1)(ii)-(iv). Also, unlike the prior Order, the Emergency Rule was formally published in the New York Register and was accompanied by a full set of required documentation, including a Regulatory Impact Statement and findings to support the need for emergency action. Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 6, 6-9, 2021 NY Reg Text 593545 (Sept. 15, 2021), Spiegelman Decl., **Exhibit D**.

The Emergency Rule contains only a single exception to its vaccination requirements, providing a narrow medical exemption that is limited in duration and scope: Employees are only exempt if a “COVID-19 vaccine [would be] detrimental to” their health “based upon a pre-existing health condition.” 10 N.Y.C.R.R. § 2.61(d)(1). As to duration, the exemption applies “only until such immunization is found no longer to be detrimental to such personnel member’s health,” and that duration “must be stated in the personnel employment medical record.” *Id.* As to scope, the exemption must be “in accordance with generally accepted medical standards,” such as the “recommendations of the Advisory Committee on Immunization Practices [ACIP],” a committee that operates under the auspices of the CDC. *Id.*

DOH guidance on the Emergency Rule makes clear that the available grounds for a medical exemption are narrow and, in practice, are largely temporary. As explained by DOH's "Frequently Asked Questions (FAQs)" regarding the Emergency Rule, the only "contraindications" recognized by the CDC as a ground for a valid medical exemption are severe or immediate allergic reactions "after a previous dose" of the vaccine or "to a component of the COVID-19 vaccine."²⁴ Even then, the CDC advises that "the majority of contraindications are temporary," such that "vaccinations often can be administered later when the condition leading to a contraindication no longer exists."²⁵

In accompanying administrative materials, DOH further explained the basis for the Emergency Rule. It noted that the Rule responded to the increasing circulation of the Delta variant, which had led to a tenfold increase in COVID-19 infections since early July 2021. DOH found that COVID-19 vaccines are safe and effective, and that the presence of unvaccinated personnel in healthcare settings poses "an unacceptably high risk" that they may acquire COVID-19 and transmit the virus to colleagues, thereby "exacerbating staffing shortages" and "causing [an] unacceptably high risk of complications" to "vulnerable patients or residents." Spiegelman Decl., Ex. D at 3. DOH emphasized that unvaccinated individuals have eleven times the risk of being hospitalized with COVID-19. *Id.*

On November 24, 2021, DOH reissued the Emergency Rule with minor modifications. The DOH observed that the initial mandate had "greatly increased the percentage of health care

²⁴ DOH, *Frequently Asked Questions (FAQs) Regarding the August 26, 2021—Prevention of COVID-19 Transmission by Covered Entities Emergency Regulation 4*, Spiegelman Decl. **Exhibit E**. Note that since the DOH FAQs were issued, the CDC has set forth a third contraindication for those taking the Janssen COVID-19 vaccine: thrombosis (blood clot formation) following receipt of a prior dose of the Janssen COVID-19 vaccine. CDC, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, available at <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications> (last visited Jan. 26, 2022).

²⁵ CDC, *Vaccine Recommendations and Guidelines of the ACIP, Contraindications and Precautions*, available at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html> (last visited January 26, 2022).

workers who are vaccinated against COVID-19” and that “[t]hese regulations are helping New York State reduce sickness and death from COVID-19. Prevention of COVID-19 Transmission by Covered Entities, 43 N.Y. Reg. 4, 4-8, 2021 NY Reg Text 601321 (Dec. 15, 2021), attached to the Spiegelman Decl., **Exhibit F**.²⁶

D. This Lawsuit

This lawsuit was filed on September 2, 2021, challenging the constitutionality of the Emergency Rule’s lack of a religious exemption. The plaintiffs are We The Patriots USA, Inc., a membership organization purportedly dedicated to “promoting constitutional rights,” and three individual healthcare workers allegedly subject to the Emergency Rule: Diane Bono, Michelle Melendez, and Michelle Synakowski. *Id.* ¶¶ 3-6. The defendants are the New York Governor and DOH Commissioner, named in their official capacities. Compl. ¶¶ 7-8.

Plaintiffs allege that they have religious objections to receiving a vaccine that uses “a fetal cell line for development, manufacturing, or testing,” *id.* ¶ 10, and that the omission of a religious exemption will require two of the plaintiffs (Melendez and Synakowski) to choose whether to take the vaccination “or lose their employment.” *Id.* ¶ 11.

Plaintiffs further allege that the State subjected them to a “bait and switch” by announcing a summary order with a religious exemption on August 16, 2021, and then issuing the Emergency Rule ten days later without such an exemption. *Id.* ¶¶ 19-21, 26. Plaintiffs claim that the Emergency Rule violates their right to free exercise of religion under the First Amendment, as well as their fundamental rights to privacy and medical freedom, which they

²⁶ The Rule was also proposed as a standard, non-emergency, regulation. *Id.* The 60-day comment period ends on February 14, 2022. *Id.* The Rule was reissued again on January 21, 2022 with an additional requirement that healthcare workers receive booster shots. Prevention of COVID-19 Transmission by Covered Entities (Jan. 21, 2022), attached to the Spiegelman Declaration as **Exhibit G**.

claim arise from “the First, Fourth, Fifth, and Fourteenth Amendments.” *Id.* ¶¶ 23-34. The Complaint seeks declaratory and injunctive relief. *Id.* at pp. 7-8.

On September 12, 2021, Plaintiffs moved for a temporary restraining order and preliminary injunction, and this Court summarily denied the motions. ECF Minute Entry, September 12, 2021. The Second Circuit affirmed the Court’s decision on October 29, 2021.

In a detailed opinion issued six days later, the Second Circuit explained why Plaintiffs were unlikely to succeed on the merits of their claims. The Court found that Plaintiffs were unlikely to prevail on their free exercise claims because they failed to show that the Emergency Rule was not “neutral” or “generally applicable.” *Patriots*, 17 F.4th at 281. Plaintiffs had not demonstrated that the Emergency Rule intentionally targeted religion because, among other things, it is consistent with earlier State vaccination programs for health care workers that likewise do not include religious exemptions. *Id.* at 282-83. The Circuit found that the Rule’s medical exemption was not comparable to Plaintiffs’ proposed religious exemption because the medical exemption protects the health of healthcare employees who would be physically harmed by a vaccine. *Id.* at 285. The Circuit also rejected Plaintiffs’ substantive due process claims, reasoning that both the Second Circuit and the Supreme Court had found that vaccine mandates issued during public health crises do not violate individuals’ fundamental rights. *Id.* at 293.

Plaintiffs’ motion in the Supreme Court for an emergency stay of the Rule was denied on December 13, 2021. *Dr. A. v. Hochul*, __ U.S. __, 142 S. Ct. 552 (2021).

This Court granted Defendants leave to file a motion to dismiss on December 27, 2021.

Legal Standards

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The “reviewing court [must]

draw on its judicial experience and common sense” to determine plausibility. *Id.* at 677. This standard places a very real burden on the plaintiff, whose claim cannot go forward if it offers merely “labels and conclusions” or “naked assertions devoid of further factual enhancement.” *Id.* at 678. A court accepts as true only the well-pled facts. *Id.* On a dismissal motion, the court may consider documents incorporated by reference in the complaint and may take judicial notice of public documents, including statutes, regulations, legislative history, and case law. *See Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 75 (2d Cir. 1998); *Wang v. Pataki*, 396 F. Supp. 2d 446, 453 n.1 (S.D.N.Y. 2005).

Argument

I. Courts—including This Court—Have Long Upheld Mandatory Vaccination Requirements, Including Those Without Religious Exemptions

Courts have long held that mandatory vaccination laws constitute a valid exercise of the State’s police powers, and such laws have withstood challenges on various constitutional grounds for more than a century.

In 1905, the Supreme Court held that mandatory vaccination laws do not offend “any right given or secured by the Constitution” and that the State’s police powers allow imposition of “restraints to which every person is necessarily subject for the common good.” *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905). In 1922, the Court cited *Jacobson* when reiterating that settled law allowed States to use their police powers to impose compulsory vaccination. *Zucht v. King*, 260 U.S. 174, 176 (1922). Indeed, the Second Circuit reaffirmed in this case just a few months ago that “*Jacobson* remains binding precedent.” 17 F.4th at 293 n.35 (“[F]or over 100 years [*Jacobson*] has stood firmly for the proposition that the urgent public health needs of the community can outweigh the rights of an individual to refuse vaccination.”).

The courts have made it clear that generally applicable vaccination requirements do not infringe on religious liberties. As the Supreme Court held over seventy years ago, “[t]he right to practice [one’s] religion freely does not include liberty to expose the community . . . to communicable disease.” *Prince v. Mass.*, 321 U.S. 158, 166-67 & n.12 (1944). More recently, the Supreme Court specifically identified “compulsory vaccination laws” as among the neutral, generally applicable laws that did not require religious exemptions under the First Amendment. *Employment Div., Dep’t of Human Res. of Ore. v. Smith*, 494 U.S. 872, 889 (1990).

Closer to home, this Court dismissed parents’ First Amendment challenge to the requirements for obtaining a religious exemption from the State’s childhood immunization law. *Phillips*, 27 F. Supp. 3d at 312-13 (Kuntz, J.). In doing so, this Court cited with approval several other cases from courts in the Eastern District of New York, which held “that no constitutional right to religious exemptions exists and found that the statutory exemption New York provides ‘goes beyond what the Supreme Court declared the First Amendment to require.’” *Id.* (quoting *Sherr v. Northport-East Northport Union Free School District*, 672 F. Supp. 81, 88 (E.D.N.Y. 1987)). The Second Circuit affirmed that decision and endorsed its reasoning, holding that “New York could constitutionally require that all children be vaccinated in order to attend public school” without any religious exemption at all, and that such an exemption “goes beyond what the Supreme Court requires.” *Phillips*, 775 F.3d at 543. Like *Jacobson*, *Phillips* remains good law. *Patriots*, 17 F.4th at 293.

In light of the settled law upholding vaccination requirements, including those without religious exemptions, Plaintiffs fail to plausibly allege that the Emergency Rule violates any of their constitutional rights, including their right to free exercise. For this reason alone, the Complaint should be dismissed.

II. Plaintiffs' Free Exercise Claims Should Also Be Dismissed Because the Emergency Rule is Neutral and Generally Applicable

It is well-established that the right to free exercise of religion does not relieve an individual of the obligation to comply with a “valid and neutral law of general applicability.” *Smith*, 494 U.S. at 879. A rational basis is all that is required to uphold neutral laws of general applicability, *i.e.*, a law that do not target, disapprove of, or single out religious groups or practices, even if it “proscribes (or prescribes) conduct that [one’s] religion prescribes (or proscribes).” *Id.* Here, rational basis review applies because the Emergency Rule is both neutral and generally applicable.

A. The Emergency Rule is Neutral

To analyze neutrality, courts first consider whether the enactment is neutral on its face, and then examine whether its purpose is to target religious conduct. *Patriots*, 17 F.4th at 281 (“A law may be not neutral if it explicitly singles out a religious practice, but even a facially neutral law will run afoul of the neutrality principle if it ‘targets religious conduct for distinctive treatment.’”) (quoting *Church of Lukumi Babalu Aye, Inc. v. City of Hialeah*, 508 U.S. 520, 533-34 (1993)).

Here, the Second Circuit has already determined that the Emergency Rule “is facially neutral because it does not single out employees who decline vaccination on religious grounds. It applies to all ‘personnel,’ as carefully defined in the Rule, aside from those who qualify for the narrowly framed medical exemption.” *Id.* The Circuit has further held that the Emergency Rule does not “target” religious conduct. “[It] requires all covered employees who can safely receive the vaccine to be vaccinated . . . and it applies whether an employee’s opposition or reluctance is due to philosophical or political objections to vaccine requirements, concerns about the vaccine’s efficacy or potential side effects, or religious beliefs.” *Id.* at 282.

Further, the Rule's neutrality is supported by the history of DOH regulation in this area. As noted above, for decades DOH has required many employees of hospitals and other healthcare facilities to be vaccinated against measles and rubella. *See supra* p. 4. Like the Emergency Rule, these healthcare worker vaccination mandates permitted narrow medical exemptions, but not religious exemptions.

Given that the text of the Emergency Rule is facially neutral and consistent with prior DOH regulatory programs, Plaintiffs' theory of religious discrimination is simply implausible.

Plaintiffs nevertheless point to the August 16, 2020 summary order issued by Governor Cuomo, which had a religious exemption (Compl. ¶¶ 19-21). They claim that there was a "bait and switch" when the Council adopted the Emergency Rule without such exemption ten days later after Governor Hochul took office. *Id.* ¶ 26. This contention is erroneous.

As the Second Circuit found, Plaintiffs "misconstrue" the relationship between the summary order and the Emergency Rule. *Patriots*, 17 F.4th at 282. The former was an interim measure issued by the DOH Commissioner alone and was intended to be in force for only 15 days. The Emergency Rule, in contrast, was issued following careful deliberation by the Council in a process that allowed for public input, based on specific findings made in a Regulatory Impact Statement, and was in effect for 90 days. *Id.* The Emergency Rule did not amend the summary order, rather, it was independently considered and enacted, and it did not "target" those opposed to receiving the COVID-19 vaccine on religious grounds. *Id.* at 282-83.²⁷

²⁷ In discussing neutrality, the Second Circuit noted that "factual development" could potentially be useful in explaining the adoption of the summary order and the Emergency Rule "and validate or disprove Plaintiffs' allegations." *Id.* at 283 n.20. The Circuit similarly referenced further "factual development" concerning the comparability of medical and religious exemptions in analyzing whether the Rule is generally applicable. *Id.* at 286. Notably, the Circuit's references to a potential fact investigation at a future litigation stage were *dicta*, i.e., unnecessary to decide the appeal from the denial of the preliminary injunction motion. The Circuit, in any event, did not examine the Complaint's allegations in any detail, much less decide whether it states plausible claims.

Moreover, Plaintiffs’ conjecture that Governor Hochul crafted the Emergency Rule to target religion ignores the fact that it was the Council—a non-political body of academics, scientists, and physicians—which adopted the Emergency Rule, and that the membership of the Council did not change when Governor Hochul was sworn into office.²⁸

Lastly, in briefing before the Second Circuit and Supreme Court, Plaintiffs claimed that the Emergency Rule was not neutral based on comments made by Governor Hochul one month after the Council adopted the Emergency Rule in which the Governor argued that accepting the COVID-19 vaccine was consistent with her Christian faith. However, those comments are irrelevant to this motion because “a party may not amend its complaint through statements made in its motion papers.” *Barton v. Pret A Manger (USA) Ltd.*, 535 F. Supp. 3d 225, 246 (S.D.N.Y. 2021) (citing *Wright v. Ernst & Young LLP*, 152 F.3d 169, 178 (2d Cir.1998)). In any event, the Governor’s *post hoc* comments do not demonstrate any lack of neutrality. *Patriots*, 17 F.4th at 288 (“Governor Hochul’s expression of her own religious belief as a moral imperative to become vaccinated cannot reasonably be understood to imply an intent on the part of the State to target those with religious beliefs contrary to hers; otherwise, politicians’ frequent use of religious rhetoric to support their positions would render many government actions ‘non-neutral’ under *Smith*.”).

Plaintiffs’ theory that the Governor intentionally targeted religious healthcare workers is “not a plausible conclusion” therefore should be rejected, and the Rule should be upheld as neutral. *Iqbal*, 556 U.S. at 682.

²⁸ Compare Current Council Membership List, available at https://www.health.ny.gov/facilities/public_health_and_health_planning_council/membership_list.htm (last visited Jan. 26, 2022) with Council Membership List as of July 5, 2021 http://web.archive.org/web/20210705172234/https://www.health.ny.gov/facilities/public_health_and_health_planning_council/membership_list.htm (last visited Jan. 26, 2022).

B. The Emergency Rule is Generally Applicable

Courts have identified two circumstances in which a policy may fail to be generally applicable. First, if “it ‘invites’ the government to consider the particular reason for a person’s conduct by providing ‘a mechanism for individualized exemptions.’” *Fulton v. City of Philadelphia, Penn.*, 141 S.Ct. 1868, 1877 (2021) (quoting *Smith*, 494 U.S. at 884). Second, “if it prohibits religious conduct while permitting secular conduct that undermines the government’s asserted interests in a similar way.” *Id.* Neither circumstance applies to DOH’s Emergency Rule.

1. *The Emergency Rule Does Not Provide for Discretionary, Individualized Exemptions*

The Emergency Rule does not vest any government official with broad authority to grant or deny a medical exemption. As the Second Circuit held, “the Rule provides for an objectively defined category of people to whom the vaccine requirement does not apply: employees who present a certification from a physician, physician assistant, or certified nurse practitioner attesting that they have a pre-existing health condition that renders the vaccination detrimental to their health, in accordance with generally accepted medical standards, such as those published by ACIP,[] for the period during which the vaccination remains detrimental to their health.” *Patriots*, 17 F.4th at 289 (citing 10 N.Y.C.R.R. § 2.61(d)(1)). The only discretion conferred by the Emergency Rule is on the employee’s physician, physician assistant, or certified nurse practitioner—not the employer—who must determine whether an exemption is warranted under generally accepted medical standards, and for how long.

The Second Circuit concluded that “[o]n its face, the Rule affords no meaningful discretion to the State or employers.” *Id.* Plaintiffs do not—and cannot—allege that the State has interpreted the Emergency Rule in a way that deviates from its plain text. Accordingly, the Emergency Rule is generally applicable even with the inclusion of the medical exemption. *Id.* at

288-89 (“‘The mere existence of an exemption procedure,’ absent any showing that secularly motivated conduct could be impermissibly favored over religiously motivated conduct, is not enough to render a law not generally applicable and subject to strict scrutiny.”).

2. *The Emergency Rule is Not Substantially Underinclusive*

For purposes of an Establishment Clause challenge, a law may not be generally applicable “‘if it is substantially underinclusive such that it regulates religious conduct while failing to regulate secular conduct that is at least as harmful to the legitimate government interests purportedly justifying it.’” *Id.* at 284-85 (quoting *Central Rabbinical Congress of the U.S. and Canada v. N.Y.C. Dep’t of Health & Mental Hygiene*, 763 F.3d 186, 197 (2d Cir. 2014)). “[T]he asserted government interest” justifying the regulation at issue is the focus of this comparability analysis. *Tandon v. Newsom*, 141 S.Ct. 1294, 1296 (2021). The Emergency Rule passes this test as well.

The primary purposes of the Emergency Rule are to safeguard the health of healthcare workers and the vulnerable populations whom they treat. “By protecting the health of healthcare employees to ensure they are able to continue working, [the State] aims to reduce the risk of staffing shortages that can compromise the safety of patients and residents even beyond a COVID-19 infection.” *Patriots*, 17 F.4th at 285. Plaintiffs do not challenge that the State has a legitimate interest in protecting New York’s healthcare workers.

As the Second Circuit has observed, the Emergency Rule’s medical exemption furthers this interest of the State, while a religious exemption would not. “Vaccinating a healthcare employee who is known or expected to be injured by the vaccine would harm her health and make it less likely she could work.” *Id.* There is no similar health concern in vaccinating employees who may have religious, personal, or philosophical objections to the vaccine.

Moreover, the plain text of the Emergency Rule makes clear that a religious exemption would pose a much greater risk to the public health than the medical exemption because the latter is limited in time and expires when the vaccination is no longer detrimental to the employee's health. In contrast, a sincerely held religious belief against vaccination is unlikely to change. *Patriots*, 17 F.4th at 286. Plaintiffs make no allegations to the contrary.

The Plaintiffs cannot plausibly contest the Emergency Rule's neutrality, or its general applicability. Consequently, it must be analyzed under the rational basis standard. *Id.* at 280.

C. The Emergency Rule is Plainly Related to the State's Legitimate Interest in Reducing the Incidence of COVID-19 in Hospitals and Other Critical Healthcare Facilities

Under rational basis review, laws are "accorded a strong presumption of validity." *Heller v. Doe by Doe*, 509 U.S. 312, 319 (1993). In applying this standard, a court should not pass on "the wisdom, fairness, or logic of legislative choices," *id.*, nor "subject [it] to courtroom fact finding." *F.C.C. v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993). Rather, a law will be upheld so long as it is reasonably related to a legitimate government interest. *Bryant v. New York State Educ. Dep't*, 692 F.3d 202, 218 (2d Cir. 2012). The law need not be supported by evidence or empirical data, and may be "based on rational speculation." *Beach Commc'ns*, 508 U.S. at 315. "The burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it." *Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356, 364 (1973).

The Second Circuit has already held that the Emergency Rule "easily meets" the rational basis review standard, finding that in the midst of a pandemic that has claimed the lives of tens of thousands of New Yorkers, this regulation "was a reasonable exercise of the State's power to enact rules to protect the public health." *Patriots*, 17 F.4th at 290.

Even if heightened scrutiny were applicable, the Emergency Rule would satisfy it. The

Supreme Court has ruled that promoting public health by preventing COVID-19 is “unquestionably a compelling interest.” *Roman Catholic Diocese of Bklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020). The Rule is narrowly tailored to that end. It focuses on a discrete sector where COVID-19 transmission poses heightened and unacceptable risks: employees in healthcare settings in a position to infect patients, other healthcare workers and the public if they contract COVID-19. The Emergency Rule does not apply to individuals working outside of enumerated entities in the healthcare sector, or to employees who present no risk of exposing colleagues or patients to the disease. 10 N.Y.C.R.R. § 2.61(a)(2). As DOH made clear in adopting the Rule, alternative approaches would not foster its goal of protecting public health by reducing COVID-19 transmission in healthcare settings. For example, a testing requirement would be impracticable due to the expense and burden of requiring testing of every person in a healthcare facility every day, and in any case, personnel could still contract and spread COVID-19 between tests. *See Spiegelman Aff.*, Ex. G at 13-14.

Because the Emergency Rule is narrowly tailored to protect the public health, it would withstand strict scrutiny even if such analysis were applicable.

III. Plaintiffs Cannot Allege Cognizable Substantive Due Process Claims

Finally, Plaintiffs also claim that the Emergency Rule violates their fundamental rights to medical freedom and privacy under the Due Process Clause of the Fourteenth Amendment.²⁹ These claims too are plainly unavailing.

As the Second Circuit held in this action, “[b]oth this Court and the Supreme Court have consistently recognized that the Constitution embodies no fundamental right that in and of itself

²⁹ To be sure, Plaintiffs also cite the First, Fourth, and Fifth Amendments in their pleading. However, as did the Second Circuit, this Court should evaluate Plaintiffs’ claims only under the Fourteenth Amendment because Plaintiffs fail to allege or explain “why the fundamental rights they assert may be implicated by constitutional provisions other than the Fourteenth Amendment.” *Patriots*, 17 F.4th at 293 n.34.

would render vaccine requirements imposed in the public interest, in the face of a public health emergency, unconstitutional.” *Id.* at 293.

Indeed, the Supreme Court, in *Jacobson v. Massachusetts*, upheld Massachusetts’s criminal penalties for violating a compulsory vaccination statute over the plaintiff’s Fourteenth Amendment challenge. 197 U.S. at 25-27, 39. If *Jacobson* permits mandatory vaccination on threat of criminal prosecution, then surely it permits vaccination as a potential term of employment. *Patriots*, 17 F.4th at 294 (“Vaccination is a condition of employment in the healthcare field; the State is not forcibly vaccinating healthcare workers.”). Consequently, Plaintiffs’ Fourteenth Amendment “‘challenge to the mandatory vaccination regime is . . . no more compelling than Jacobson’s was more than a century ago,’” and should be dismissed. *Id.* (quoting *Phillips*, 775 F.3d at 542); *see also Maniscalco v. New York City Dep’t of Educ.*, No. 21-2343, 2021 WL 4814767, at *1 (2d Cir. Oct. 15, 2021) (summarily affirming district court’s decision denying motion for preliminary injunction of vaccination requirement for New York City teachers predicated on substantive due process claim).

Conclusion

For the foregoing reasons, Defendants' motion to dismiss should be granted in its entirety, and the Complaint should be dismissed with prejudice.

Dated: New York, New York
January 26, 2022

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